INFRARED GENERATORS (INCLUDING HEATING PADS).

Warning—Use carefully. May cause serious burns. Do not use over insensitive skin areas or in the presence of poor circulation. The unattended use of infrared heat by children or incapacitated persons may be dangerous.

INSULIN SYRINGES.

Warning—For patients who mix two types of insulin: Do not change: (a) The order of mixing that the physician has prescribed or (b) the model and brand of the syringe or needle without first consulting your physician or pharmacist. Failure to heed this warning can result in dosage error.

MECHANICAL MASSAGERS AND VIBRATORS.

Warning—This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in unexplained calf pain. Consult physician.

STEAM OR TURKISH BATH.

Warning—Elderly persons or those suffering from heart disease or high blood pressure should not use this device unless directed by physician.

ULTRAVIOLET GENERATORS.

Warning—Wear protective goggles during use to avoid eye injury. Serious burns may be caused by exposure in excess of recommended dosage. Do not use over skin eruptions unless directed by physician.

§ 801.405 Labeling of articles intended for lay use in the repairing and/or refitting of dentures.

(a) The American Dental Association and leading dental authorities have advised the Food and Drug Administration of their concern regarding the safety of denture reliners, repair kits, pads, cushions, and other articles marketed and labeled for lay use in the repairing, refitting, or cushioning of ill-fitting, broken, or irritating dentures. It is the opinion of dental authorities and the Food and Drug Administration that to properly repair and properly refit dentures a person must have professional knowledge and specialized technical skill. Laymen cannot be expected to maintain the original vertical dimension of occlusion and the centric relation essential in the proper repairing or refitting of dentures. The continued wearing of improperly repaired or refitted dentures may cause acceleration of bone resorption, soft tissue hyperplasia, and other irreparable damage to the oral cavity. Such articles designed for lay use should be limited to emergency or temporary situations pending the services of a licensed dentist.

(b) The Food and Drug Administration therefore regards such articles as unsafe and misbranded under the Federal Food, Drug, and Cosmetic Act, unless the labeling:

(1)(i) Limits directions for use for denture repair kits to emergency repairing pending unavoidable delay in obtaining professional reconstruction of the denture;

(ii) Limits directions for use for denture reliners, pads, and cushions to temporary refitting pending unavoidable delay in obtaining professional reconstruction of the denture;

(2) Contains in a conspicuous manner the word ''emergency'' preceding and modifying each indication-for-use statement for denture repair kits and the word ''temporary'' preceding and modifying each indication-for-use statement for reliners, pads, and cushions; and

(3) Includes a conspicuous warning statement to the effect:

(i) For denture repair kits: ''*Warning—For emergency repairs only*. Long term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit for emergency use only. See Dentist Without Delay.''

(ii) For denture reliners, pads, and cushions: ''*Warning—For temporary use only*. Longterm use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until a Dentist Can Be Seen.''

(c) Adequate directions for use require full information of the temporary and emergency use recommended in order for the layman to understand the limitations of usefulness, the reasons therefor, and the importance of adhering to the warnings. Accordingly, the labeling should contain substantially the following information:

(1) For denture repair kits: Special training and tools are needed to repair dentures to fit properly. Home-repaired dentures may cause irritation to the gums and discomfort and tiredness while eating. Long term use may lead to more troubles, even permanent changes in bones, teeth, and gums, which may make it impossible to wear dentures in the future. For these reasons, dentures repaired with this kit should be used only in an emergency until a dentist can be seen. Dentures that don't fit properly cause irritation and injury to the gums and faster bone loss, which is permanent. Dentures that don't fit properly cause gum changes that may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible.

(2) For denture reliners, pads, and cushions: Use of these preparations or devices may temporarily decrease the discomfort; however, their use will not make the denture fit properly. Special training and tools are needed to repair a denture to fit properly. Dentures that do not fit properly cause irritation and injury to the gums and faster bone loss, which is permanent and may require a completely new denture. Changes in the gums caused by dentures that do not fit properly may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible.

(3) If the denture relining or repairing material forms a permanent bond with the denture, a warning statement to the following effect should be included: ''This reliner becomes fixed to the denture and a completely new denture may be required because of its use.''

(d) Labeling claims exaggerating the usefulness or the safety of the material or failing to disclose all facts relevant to the claims of usefulness will be regarded as false and misleading under sections 201(n) and 502(a) of the Federal Food, Drug, and Cosmetic Act.

(e) Regulatory action may be initiated with respect to any article found within the jurisdiction of the act contrary to the provisions of this policy statement after 90 days following the date of publication of this section in the FEDERAL REGISTER.

§ 801.408 Pessaries for intracervical and intrauterine use.

(a) Because of the limited evidence previously available concerning the hazards attending the use of intracervical and intrauterine pessaries, the shipment of such devices within the jurisdiction of the Federal Food, Drug, and Cosmetic Act with labeling limiting them to sale only on prescription, has not been subjected to regulatory proceedings. A recent survey shows that it is now the consensus of medical opinion among experts qualified by scientific training and experience to evaluate the safety of such devices that stem-type and wing-type intercervical and intrauterine pessaries are too dangerous for use under any form of labeling and serve no useful purpose. This opinion is particularly applicable to pessaries offered or intended for contraceptive use. These views do not apply to those pessaries, made with hollow tubes, intended solely for use when necessary to maintain drainage from the uterine cavity.

(b) On the basis of this consensus of expert opinion and the supporting evidence of many known injuries, the Food and Drug Administration concludes that stem-type and wing-type intracervical and intrauterine pessaries are dangerous to health, and regardless of their labeling, may be shown to be misbranded within the meaning of sections 502(f) (1) and (2) and 502(j) of the Federal Food, Drug, and Cosmetic Act. It is recommended that distributors of these devices remove them from the interstate market at once. Regulatory action may be instituted in connection with any such devices found within the jurisdiction of the act.

§ 801.410 Use of impact-resistant lenses in eyeglasses and sunglasses.

(a) Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicates that the use of such lenses constitutes an avoidable hazard to the eye of the wearer.

(b) The consensus of the ophthalmic community is that the number of eye